# **EXHIBIT 5**

### IN THE CIRCUIT COURT OF **COVINGTON COUNTY, ALABAMA**

SYLVIA WINGARD as the Administrator of the Estate of GEORGE WINGARD Plaintiff,

Plaintiff,

vs.

**CIVIL NO:** 

CV-06-32

PFIZER INC:

PHARMACIA CORPORATION; MONSANTO COMPANY; G.D. SEARLE, LLC AND ALEX DUMOULIN, JR;

Defendants.

#### **SUMMONS**

This service by certified mail of this summons is initiated upon the written request of Plaintiff's attorney pursuant to the Alabama Rules of Civil Procedure.

NOTICE TO:

PFIZER, INC.

c/o The Corporation Company, Registered Agent

2000 Interstate Park Drive, Suite 204

Montgomery, AL 36109

The Complaint, which is attached to this summons, is important and you must take immediate action to protect your rights. You are required to mail or hand-deliver a copy of a written Answer, either admitting or denying each allegation in the Complaint to,

> NAVAN WARD, JR. BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C. Post Office Box 4160 Montgomery, Alabama 36103-4160

the attorney for the Plaintiffs. THIS ANSWER MUST BE MAILED OR DELIVERED WITHIN THIRTY (30) DAYS FROM THE DATE OF DELIVERY OF THIS SUMMONS AND COMPLAINT AS EVIDENCED BY THE RETURN RECEIPT, OR A JUDGMENT BY DEFAULT MAY BE ENTERED AGAINST YOU FOR THE MONEY OR OTHER THINGS DEMANDED IN THE COMPLAINT. You must also file the original of your Answer with the Clerk of this Court within a reasonable time afterward.

FILED IN OFFICE

# IN THE CIRCUIT COURT OF COVINGTON COUNTY, ALABAMA

SYLVIA WINGARD as the Administrator \* of the Estate of GEORGE WINGARD Plaintiff, CIVIL NO. CV-06-32 vs. PFIZER INC., a Delaware Corporation; PHARMACIA CORPORATION, a Delaware Corporation; MONSANTO COMPANY, a Delaware Corporation; \* \* G.D. SEARLE, LLC, a Delaware Corporation; ALEX DUMOULIN, JR And fictitious Defendants A, B, C and D being those persons, firms \* or corporations whose actions, inactions, \* fraudulent suppression, fraud, scheme to TRIAL BY JURY IS REQUESTED × defraud and/or other wrongful conduct \* caused or contributed to the Plaintiff's ÷ injuries and damages, and whose true names and identities are presently unknown to the Plaintiff but will be substituted by amendment when FILED IN OFFICE ascertained. FEB 1 3 2006 Defendants. Des 1 Parce

### **COMPLAINT**

COMES NOW, Sylvia Wingard, (hereinafter "Plaintiff"), as the Administrator of the Estate of George Wingard, decedent in an action against Pfizer, Inc., Pharmacia Corporation, Monsanto Company, and G.D. Searle, LLC., and Alex Dumoulin, Jr. (hereinafter "Defendants"), and for Plaintiff's cause of action against the Defendants states as follows:

#### **Statement Of The Parties**

This is a civil action brought by Plaintiff, Sylvia Wingard, on behalf of George 1. Wingard deceased for injuries resulting in a stroke at death. Plaintiff was prescribed and used

Page 4 of 50

the prescription medication Bextra (Valdecoxib). This action seeks monetary damages for the wrongful death caused by Bextra and ingested by George Wingard, the deceased.

- 2. Plaintiff, Sylvia Wingard, is over the age of 19 years and is currently a resident of Covington County, Alabama.
- 3. Defendant G. D. Searle LLC (hereinafter "Searle") was a subsidiary of Pharmacia Corporation and is upon information, knowledge and belief an Illinois Corporation. At all times relevant hereto, Searle, as a subsidiary of Pharmacia Corporation, was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product Bextra (Valdecoxib). Defendant Searle is licensed and registered to do business in the State of Alabama. Defendant Searle can be served at its principle place of business: G. D. Searle, LLC; 4901 Searle Parkway; Skokie, Illinois 60077.
- Defendant Pharmacia Corporation (hereinafter "Pharmacia") is a Delaware 4. Corporation with its principal place of business in New Jersey. At all times relevant to this action. Pharmacia was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product Bextra (Valdecoxib). Defendant Pharmacia is licensed and registered to do business in the State of Alabama. Defendant Pharmacia can be served at its principle place of business: Pharmacia Corporation; 100 U.S. Highway 206 North; Peapack, New Jersey 07977.
- Defendant Monsanto Company (hereinafter "Monsanto") was the parent 5. corporation of Pharmacia and is a Delaware Corporation. At all times relevant hereto, Monsanto, through its subsidiary companies, was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product Bextra (Valdecoxib). Defendant Monsanto is licensed and registered to do business in the State of Alabama. Defendant Monsanto can be served at its principle place of business: Monsanto Company; 800 North Lindbergh Boulevard;

St. Louis, Missouri 63167.

- Defendant Pfizer, Inc. (hereinafter "Pfizer") is a Delaware corporation with its principal place of business in New York. At all times relevant hereto, Pfizer was in the business of marketing, selling and distributing the pharmaceutical product Bextra (Valdecoxib). Defendant Pfizer is licensed and registered to do business in the State of Alabama and may be served through its registered agent at Pfizer, Inc., c/o The Corporation Company; 2000 Interstate Park Drive, Suite 204; Montgomery, Alabama 36109.
- 7. Defendant Alex Dumoulin, Jr. at all times material hereto was a sales representative for Defendant G. D. Searle, Pharmacia, Monsanto and Pfizer (hereinafter collectively referred to as "Pfizer") and was acting within the coarse and scope of their employment with the Pfizer Defendant's. Upon information and belief, Defendant Dumoulin is a resident of Alabama and, at all times material hereto, was in the business of marketing selling and distributing Bextra. Defendant Dumoulin can be served at his home address: 5860 Main Street, Apartment 506, Millbrook, AL 36054.
- Personal jurisdiction and subject matter jurisdiction are appropriate in this court 8. as to all Defendants, as all Defendants have done business in Covington County, Alabama, either directly or by agent, and have thus availed themselves of this jurisdiction.
- The Plaintiff's claims accrued in whole or in part in Covington County, Alabama 9. and the Plaintiff resided in Covington County, Alabama at the time of Plaintiff's injury. Plaintiff ingested Bextra (Valdecoxib) in and while residing in Covington County, Alabama. Some of these Defendants are foreign corporations, which have been and are currently engaged in business, directly or by authorized agent, in Covington County, Alabama. Upon information and belief, the Sales Representatives are individuals who, at all time material hereto, transacted

business in Covington City, Alabama. Venue and jurisdiction are therefore proper. The claims of Plaintiff herein satisfy the jurisdictional amount of this court.

- 10. Pfizer Defendants marketed and distributed this drug in Covington County, Alabama. Defendants encouraged the use of this drug in improper customers, misrepresented the safety and effectiveness of this drug and concealed or understated its dangerous side effects in Covington County, Alabama. These Defendants aggressively marketed this drug directly to the consuming public through the use of various marketing mediums, including, but not limited to, print and television advertisements in Covington County, Alabama.
- Based on information and belief, Sales Representatives called on physicians, 11. including Plaintiff's physician on numerous occasions at which times they presented fraudulent information regarding the safety and efficacy of Bextra and its harmful side effects, and/or fraudulently suppressed material information regarding the safety and efficacy of Bextra and its harmful side effects, and/or placed Bextra in the stream of commerce by providing Plaintiff's physician(s) samples of the drug Bextra.
- At all times material hereto, the Defendants Sales Representatives advertised, 12. marketed, and/or promoted Bextra to Plaintiff's prescribing physician utilizing information known to fraudulently represent the safety and efficacy of Bextra and the Sales Representatives failed to warn of the known dangers and adverse events associated with the use of the drug Bextra.
- At all times material hereto, the Defendant Sales Representatives placed Bextra in 13. the stream of commerce by distributing to physicians, including Plaintiff's physician, numerous samples of Bextra at varying doses.
  - At all times relevant hereto, the Defendants actually knew of the defective nature 14.

Page 7 of 50

of their product as herein set forth, yet continued to design, manufacture, market, distribute and sell their product in Covington County, Alabama. Defendants' conduct exhibits an entire want of care as to the safety of this product and a conscious disregard of the foreseeable harm caused by this product in Covington County, Alabama.

#### Statement of the Facts

- 15. At all times relevant hereto, Defendants were engaged in the business of designing, testing, inspecting, manufacturing, assembling, developing, labeling, sterilizing, licensing, marketing, advertising, promoting, selling, packaging, supplying and/or distributing the pharmaceutical drug Bextra (Valdecoxib) throughout the United States.
- 16. Bextra is a pharmaceutical treatment for musculoskeletal joint pain associated with osteoarthritis, among other maladies. Defendants did manufacture, design, package, market and distribute this drug. Defendants encouraged the use of this drug in improper customers, misrepresented the safety and effectiveness of this drug and concealed or understated its dangerous side effects. These Defendants aggressively marketed this drug directly to the consuming public, although only available through prescription, through the use of various marketing mediums, including, but not limited to, print and television advertisements. These Defendants did this to increase sales and profits.
- Defendants, at all times relevant hereto, knew of the defective nature of their 17. product as herein set forth, yet continued to design, manufacture, market, distribute and sell their product so as to maximize sales and profits at the expense of the general public's health and safety in conscious disregard of the foreseeable harm caused by this product. Defendants' conduct exhibits such an entire want of care as to establish that their actions were a result of fraud, ill will, recklessness, gross negligence or willful and intentional disregard to the Plaintiff's individual rights, and hence punitive damages are appropriate.

- 18. George Wingard was 44 years old on or about March 11, 2005, when he died from a stoke due to his use of Bextra (Valdecoxib).
- 19. This Complaint seeks redress for damages sustained by George Wingard, resulting from the use of Bextra (Valdecoxib), manufactured and sold by the Defendants.
- The damages sought herein are the direct and proximate result of Defendants' 20. wrongful conduct in connection with designing, testing, inspecting, manufacturing, assembling, developing, labeling, sterilizing, licensing, marketing, advertising, promoting, selling, packaging, supplying and/or distributing the prescription drug Bextra (Valdecoxib).
- 21. Had Defendants properly disclosed the risks associated with using Bextra (Valdecoxib), Plaintiff would not have taken it for treatment of pain associated with injury.
- 22. This action is being brought in the Circuit Court of Covington County, because the amount of recovery sought exceeds the jurisdictional levels of all lower courts.

### FIRST CAUSE OF ACTION **NEGLIGENCE**

- 23. Plaintiff repeats and realleges each of the allegations contained in this Complaint.
- Defendants, directly or indirectly, negligently and/or defectively designed, tested, 24. inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed the drug Bextra (Valdecoxib).
- At all times material hereto, Defendants had a duty to users and/or consumers of 25. Bextra (Valdecoxib), including Plaintiff, to exercise reasonable care in the design, testing, inspection, manufacture, assembly, development, labeling, sterilization, licensing, marketing, advertising, promotion, sale, packaging, supply and/or distribution of Bextra (Valdecoxib).
- Defendants breached that duty and were negligent in the design, testing, 26. inspection, manufacture, assembly, development, labeling, sterilization, licensing, marketing, advertising, promotion, sale, packaging, supply and/or distribution of Bextra (Valdecoxib) in

that: Bextra (Valdecoxib) was defective when put on the market by Defendants; that with such defect, Bextra (Valdecoxib) was reasonably certain to be dangerous when put to normal use; and that Defendants failed to use reasonable care in designing or making Bextra (Valdecoxib) or in inspecting it for defects. Specifically, Defendants breached their duty by, among other things:

- Failing to include adequate warnings that would alert the medical, a. pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, to the potential risks and serious side effects of the drug;
- Failing to adequately and properly test and inspect the drug before placing b. the drug on the market;
- Failing to conduct sufficient testing and inspection of the drug which, if C. properly performed, would have shown that the drug had serious side effects, including, but not limited to, stroke, heart attack, life threatening allergic and/or skin reactions and/or death.
- d. Failing to adequately warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and other serious side effects associated with the drug, including, but not limited to, stroke, heart attack, life threatening allergic and/or skin reactions and/or death;
- Failing to provide adequate post-marketing warnings or instructions after e. Defendants knew or should have known of the significant risks associated with the use of the drug;
- Failing to recall and/or remove the drug from the stream of commerce f. despite the fact that Defendants knew or should have known of the defective and unreasonably dangerous nature of the drug, including the significant health risks associated with the use of the drug;

- Encouraging misuse and overuse while failing to disclose the side effects g. of the drug to the medical, pharmaceutical and/or scientific communities, and users and/or consumers, including Plaintiff, in order to make a profit from sales.
- Defendants knew or should have known that Bextra (Valdecoxib) caused 27. unreasonably dangerous risks and serious side effects of which users and/or consumers of the drug, including Plaintiff, were not aware. Defendants nevertheless advertised, promoted, marketed, sold, distributed and/or supplied Bextra (Valdecoxib) knowing that there were safer methods for pain relief.
- As a direct, legal, proximate and producing result of the negligence of 28. Defendants, Plaintiff sustained substantial injuries including, among other things, a stroke resulting in death. This injury caused extensive pain and suffering and severe emotional distress and negated Plaintiff's ability to enjoy life. In addition, Defendants' negligence caused Plaintiff to expend substantial sums of money for medical, hospital, and funeral expenses.
- As a direct, legal, proximate and producing result of the negligence of 29. Defendants, Plaintiff was injured in health, strength and activity and suffered physical injuries as well as mental anguish, which resulted in death.
- As a direct, legal, proximate and producing result of the negligence of 30. Defendants, Plaintiff required reasonable and necessary health care treatment and services and had incurred expenses therefore. Defendants' negligence was a contributing cause of Plaintiff's death.
- By reason of the foregoing, Plaintiff was damaged by the negligence and wanton 31. and willful recklessness of the Defendants. The amount sought herein exceeds the jurisdictional limits of all lower courts that would otherwise have jurisdiction over this matter.

8

### SECOND CAUSE OF ACTION STRICT PRODUCTS LIABILITY DEFECTIVE DESIGN

- 32. Plaintiff repeats and realleges each of the allegations contained in this Complaint.
- 33. At all times material hereto, Defendants have engaged in the business of designing, testing, inspecting, manufacturing, assembling, developing, labeling, sterilizing, licensing, marketing, advertising, promoting, selling, packaging, supplying and/or distributing the drug Bextra (Valdecoxib), which is defective and unreasonably dangerous to users and/or consumers of the drug, including Plaintiff.
- 34. At all times material hereto, Bextra (Valdecoxib) was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendants in a defective and unreasonably dangerous condition in ways which include, but are not limited to, one or more of the following:
  - a. When placed in the stream of commerce, the drug contained unreasonably dangerous design defects and was not reasonably safe and fit for its intended or reasonably foreseeable purpose or as intended to be used, thereby subjecting users and/or consumers of the drug, including Plaintiff, to risks which exceeded the benefits of the drug;
    - b. The drug was insufficiently tested;
    - c. The drug caused harmful side effects that outweighed any potential utility;
  - d. The drug was not accompanied by adequate labeling or instructions for use to fully apprise the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and serious side effects associated with its use;

- In light of the potential and actual risk of harm associated with the drug's e. use, a reasonable person who had actual knowledge of this potential and actual risk of harm would have concluded that Bextra (Valdecoxib) should not have been marketed in that condition.
- At all times the drug Bextra (Valdecoxib) was designed, tested, inspected, 35. manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed, it was expected to reach, and did reach, users and/or consumers of the drug across the United States, including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was sold.
- At all times, Plaintiff used Bextra (Valdecoxib) for its intended or reasonably 36. foreseeable purpose.
- 37. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Bextra (Valdecoxib), Plaintiff sustained substantial injuries including, among other things, a stroke, resulting in death. These injuries caused extensive pain and suffering and severe emotional distress and negated Plaintiff's ability to enjoy life. In addition, the defective and unreasonably dangerous condition of Bextra (Valdecoxib) caused Plaintiff to expend substantial sums of money for medical, hospital, and funeral expenses.
- As a direct, legal, proximate and producing result of the defective and 38. unreasonably dangerous condition of Bextra (Valdecoxib), Plaintiff was injured in health, strength and activity and suffered physical injuries as well as mental anguish, which resulted in death.
- As a direct, legal, proximate and producing result of the defective and 39. unreasonably dangerous condition of Bextra (Valdecoxib), Plaintiff required reasonable and necessary health care treatment and service and had incurred expenses therefore. The defective and unreasonably dangerous condition of Bextra (Valdecoxib) was a contributing cause of Plaintiff's death.

40. By reason of the foregoing, Plaintiff was damaged by the wanton and willful recklessness of the Defendants, who will be liable to Plaintiff. The amount sought herein exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this matter.

### THIRD CAUSE OF ACTION STRICT PRODUCTS LIABILITY FAILURE TO WARN

- 41. Plaintiff repeats and realleges each of the allegations contained in this Complaint.
- 42. Bextra (Valdecoxib) was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, to the dangerous risks and reactions associated with Bextra (Valdecoxib) when used for its intended or reasonably foreseeable purpose. Those dangerous risks and reactions included, but were not limited to, stroke, heart attack, life threatening allergic and/or skin reactions, other serious and life threatening side effects, and/or death.
- 43. At all times, Plaintiff's decedent used the drug for its intended or reasonably foreseeable purpose.
- 44. Plaintiff's decedent could not have discovered any defect in the drug through the exercise of care.
- 45. Defendants, as manufacturers of a prescription drug, is held to the level of knowledge of an expert in the field.
- 46. The warnings that were given by Defendants were not accurate or clear and/or were ambiguous.
- 47. Defendants had a continuing duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and serious side effects associated with the use of Bextra (Valdecoxib).

- As a direct, legal, proximate and producing result of Defendant's failure to warn, 48. Plaintiff sustained harm, including, among other things, a stroke, resulting in death. These injuries caused extensive pain and suffering and severe emotional distress and negated Plaintiff's ability to enjoy life. In addition, Defendants' failure to warn caused Plaintiff to expend substantial sums of money for medical, hospital, and funeral expenses.
- As a direct, legal, proximate and producing result of Defendants' failure to warn, 49. Plaintiff was injured in health, strength and activity and suffered physical injuries as well as mental anguish, which resulted in death.
- As a direct, legal, proximate and producing result of Defendants' failure to warn, 50. Plaintiff required reasonable and necessary health care treatment and services and had incurred expenses therefore. The Defendant's failure to warn was a contributing cause of Plaintiff's death.
- By reason of the foregoing, Plaintiff was damaged by the wanton and willful 51. recklessness of the Defendants who will be liable to Plaintiff. The amount sought herein exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this matter.

### FOURTH CAUSE OF ACTION BREACH OF EXPRESS WARRANTY OF MERCHANTABILITY

- Plaintiff realleges all prior paragraphs of this complaint as if fully set out herein. 52.
- Defendants made express representations to the consuming public at large through 53. their aggressive marketing and advertising campaigns relative to their product, Bextra.
- Defendants, through their agents and/or sales representatives, made 54. representations of the safety and efficacy of their product, Bextra.
- Bextra does not conform to the express representations made through the 55. Defendants' advertising and marketing efforts

- 56. Bextra does not conform to the express representations made by Defendants' agents and/or sales representatives.
- 57. As a direct, legal, proximate and producing result of the express representations made by Defendants', through their advertising and marketing efforts, and by their agents and/or sales representatives, Plaintiff sustained harm. Defendants' conduct in this matter was a contributing cause of Plaintiff's stroke which resulted in death.
- 58. Wherefore, this Plaintiff demands judgment against Defendants in such an amount of compensatory and punitive damages as a jury deems reasonable, plus cost.

# FIFTH CAUSE OF ACTION BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

- 59. Plaintiff repeats and realleges each of the allegations contained in the Complaint.
- 60. Defendant is a "merchant" as defined in Alabama Code § 7-2-104.
- 61. Bextra (Valdecoxib) is a "good" as defined Alabama Code § 7-2-105.
- 62. At the time that Defendants designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed the drug Bextra (Valdecoxib), Defendants knew of the intended, reasonably foreseeable and/or ordinary use of Bextra (Valdecoxib) and impliedly warranted the drug to be of merchantable quality and safe and fit for such use.
- 63. Plaintiff, in ingesting Bextra (Valdecoxib), reasonably relied upon the skill and judgment of Defendants as to whether Bextra (Valdecoxib) was of merchantable quality and safe and fit for its intended, reasonably foreseeable and/or ordinary use.
- 64. In breach of the implied warranty given by Defendants, Bextra (Valdecoxib) was not of merchantable quality or safe or fit for its intended, reasonably foreseeable and/or ordinary use because the product was and is unmerchantable, in a defective condition and unreasonably

dangerous and unfit for the intended, reasonably foreseeable and/or ordinary purpose for which it was intended as described above.

- 65. In breach of the implied warranty given by Defendants, Bextra (Valdecoxib) was not of merchantable quality or safe or fit for its intended, reasonably foreseeable and/or ordinary use because, among other things:
  - Use of Bextra (Valdecoxib) carried a risk of, among other things, a stroke, a. heart attack and/or death and other serious and life threatening side effects:
  - Defendants failed to include adequate warnings with the drug that would b. alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and serious side effects of the drug;
  - c. Defendants failed to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the potential risks and serious side effects associated with the use of the drug.
- 66. As a direct, legal, proximate and producing result of Defendants' breach of warranty, Plaintiff sustained substantial injuries including, among other things, a stroke, resulting in death. These injuries caused extensive pain and suffering and severe emotional distress and negated Plaintiff's ability to enjoy life. In addition, Defendants' breach of warranty caused Plaintiff to expend substantial sums of money for medical, hospital and funeral expenses.
- As a direct, legal, proximate and producing result of Defendants' breach of 67. warranty, Plaintiff has been injured in health, strength and activity and suffered physical injuries as well as mental anguish, which resulted in death.
- As a direct, legal, proximate and producing result of Defendants' breach of 68. warranty, Plaintiff required reasonable and necessary health care treatment and services and had incurred expenses therefore. Defendant's breach of warranty was a contributing case of Plaintiff's death.

69. By reason of the foregoing, Plaintiff has been damaged by the wanton and willful recklessness of the Defendants who will be liable to Plaintiff. The amount sought herein exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this matter.

# SIXTH CAUSE OF ACTION

- Plaintiff repeats and realleges each of the allegations contained in the Complaint. 70.
- 71. Defendants recklessly, knowingly, intentionally, and fraudulently misrepresented to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, the safety and efficacy of the drug and/or recklessly, knowingly, intentionally and fraudulently concealed from the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, material, adverse information regarding the safety and efficacy of Bextra (Valdecoxib).
- 72. Defendants' misrepresentations were communicated to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, with the intent that they reach users and/or consumers of the drug, including Plaintiff.
  - Defendants either knew or should have known that the representations were false. 73.
- 74. Defendants made the misrepresentations and/or actively concealed information concerning the safety and efficacy of the drug with the intention and specific desire that the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, would rely on such in selecting Bextra (Valdecoxib) as a pain reliever.
- Defendants made these misrepresentations and/or actively concealed information 75. concerning the safety and efficacy of Bextra (Valdecoxib) in its labeling, advertising, product inserts, promotional materials or other marketing efforts.

- 76. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or should have known that its drug product had defects, dangers and characteristics that were other than what Defendants had represented to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff. Specifically, Defendants misrepresented to and/or actively concealed from the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, that:
  - There had been insufficient studies regarding the safety and efficacy of the a. drug;
  - b. The drug was fully and adequately tested, despite knowing that there had been insufficient or inadequate testing of the drug;
  - Prior studies, research, reports and/or testing had been conducted linking ¢. the use of the drug to serious prothrombotic and allergic and/or skin reactions, including, but not limited to, adverse cardiovascular events and/or Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis;
  - Defendants knew or should have known of reports of increased heart d. attacks, allergic and/or skin reactions and/or strokes associated with the use of the drug;
  - Defendants knew or should have known of the greatly increased risk of ę. developing heart attacks, allergic and/or skin reactions and/or strokes associated with use of Bextra (Valdecoxib); yet, despite this they were downplaying the risk of the drug.
- The misrepresentations of and/or active concealment by Defendants were 77. perpetuated directly and/or indirectly by Defendants, its sales representatives, employees, distributors, agents and/or detail persons.
- The misrepresentations of and/or active concealment by Defendants constitute a 78. continuing tort. Indeed, through Defendants' product inserts, Defendants continued to misrepresent the potential risks and serious side effects associated with the use of Bextra

(Valdecoxib). Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, about the potential risks and serious side effects associated with the use of Bextra (Valdecoxib) in a timely manner, yet they failed to provide such warning.

- 79. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest Bextra (Valdecoxib) to Plaintiff's detriment.
- As a direct, legal, proximate and producing result of the misrepresentations of 80. Defendants, Plaintiff sustained substantial injuries including, among other things, a stroke, resulting in death. These injuries caused extensive pain and suffering and severe emotional distress for Plaintiff, and negated Plaintiff's ability to enjoy life. In addition, the misrepresentations of Defendants caused Plaintiff to expend substantial sums of money for medical, hospital, and funeral expenses.
- As a direct, legal, proximate and producing result of the misrepresentations of 81. Defendants, Plaintiff has been injured in health, strength and activity and suffered physical injuries as well as mental anguish, which resulted in death.
  - As a result of Defendants' fraud, Plaintiff suffered a stroke resulting in death. 82.
- As a direct, legal, proximate and producing result of the misrepresentations of 83. Defendants, Plaintiff required reasonable and necessary health care treatment and service and had incurred expenses therefore.
- By reason of the foregoing, Plaintiff has been damaged by the wanton and willful 84. recklessness of the Defendants who will be liable to Plaintiff. The amount sought herein exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this matter.

# SEVENTH CAUSE OF ACTION NEGLIGENT MISREPRESENTATION

- 85. Plaintiff repeats and realleges each of the allegations contained in the Complaint.
- 86. Defendants negligently misrepresented or failed to exercise reasonable care in representing to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, the safety and efficacy of the drug and/or negligently concealed or failed to exercise reasonable care by concealing and failing to disclose to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, material, adverse information regarding the safety and efficacy of Bextra (Valdecoxib).
- 87. Defendants' misrepresentations were communicated to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, with the intent that they reach users and/or consumers of the drug, including Plaintiff.
- 88. Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of Bextra (Valdecoxib) in its labeling, advertising, product inserts, promotional materials or other marketing efforts.
  - 89. Defendants either knew or should have known that the representations were false.
- 90. Defendants knew or should have known that the misrepresentations and/or omissions concerning the safety and efficacy of the drug would be relied upon by the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, in selecting Bextra (Valdecoxib) as a pain reliever.
- 91. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or should have known that its drug product had defects, dangers and characteristics that were other than what Defendants had represented to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff. Specifically, Defendants misrepresented to and/or actively concealed from

the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, that:

- There had been insufficient studies regarding the safety and efficacy of the a. drug;
- The drug was fully and adequately tested, despite the fact that there had b. been insufficient or inadequate testing of the drug;
- c. Prior studies, research, reports and/or testing had been conducted linking the use of the drug to serious adverse cardiovascular events, allergic and/or skin reactions and strokes;
- d. Defendants knew or should have known of reports of strokes associated with the use of the drug;
- Defendants knew or should have known of the greatly increased risk of e. heart attacks, strokes, life threatening allergic and/or skin reactions and/or death and other serious and life threatening side effects associated with the drug; yet, despite this was downplaying the risks of the drug.
- The misrepresentations of and/or active concealment by Defendants were 92. perpetuated directly and/or indirectly by Defendants, their sales representatives, employees, distributors, agents and/or detail persons.
- The misrepresentations of and/or active concealment by Defendants constitute a 93. continuing tort. Indeed, through Defendants' product inserts, Defendants continued to misrepresent the potential risks and complications associated with Bextra (Valdecoxib). Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, about the potential risks and serious side effects associated with the use of Bextra (Valdecoxib) in a timely manner, yet it failed to provide such warning.

- Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or 94. active concealment of Defendants to purchase and ingest Bextra (Valdecoxib) to Plaintiff's detriment.
- As a direct, legal, proximate and producing result of the misrepresentations of 95. Defendants, Plaintiff sustained harm, including, among other things, a stroke, resulting in death. These injuries have caused extensive pain and suffering and severe emotional distress and negated Plaintiff's ability to enjoy life. In addition, the misrepresentations of Defendants caused Plaintiff to expend substantial sums of money for medical, hospital, and funeral expenses.
- As a direct, legal, proximate and producing result of the misrepresentations of 96. Defendants, Plaintiff was injured in health, strength and activity and suffered physical injuries as well as mental anguish, which resulted in death.
- As a direct, legal, proximate and producing result of the misrepresentations of 97. Defendants, Plaintiff required reasonable and necessary health care treatment and service and had incurred expenses therefore.
- As a result of the negligent misrepresentations of the Defendants, Plaintiff 98. suffered a stroke resulting in death.
- By reason of the foregoing, Plaintiff has been damaged by the wanton and willful 99. recklessness of these Defendants who will be liable to Plaintiff. The amount sought herein exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction over this matter.

# EIGHTH CAUSE OF ACTION WRONGFUL DEATH

- Plaintiff repeats and re-alleges each of the allegations contained in this Complaint. 100.
- Plaintiff brings this wrongful death count pursuant to Alabama Code §6-5-410. 101.
- As a direct and proximate result of the conduct of Defendants and/or the defective 102. nature of the product as outlined above, Plaintiff's decedent, George Wingard, suffered bodily

injury and resulting pain and anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses of hospitalization, medical nursing care and treatment, loss of earnings, loss of ability to earn money and eventually, death.

- 103. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has incurred hospital, nursing, and medical expenses. Plaintiff has incurred hospital, nursing, medical, funeral and estate administration expenses as a result of his decedent's death. Plaintiff, Wrongful Death Beneficiaries, bring this claim on behalf of her decedent's lawful beneficiaries for these damages and for all pecuniary losses sustained by said beneficiaries.
- By reason of the foregoing Plaintiff, on behalf of her decedent, George Wingard, 104. demands judgment against Defendants for damages, both compensatory and punitive, interest, attorneys' fees, costs of suit as provided by law, and such other relief as the Court may deem just and equitable.

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that the Defendants be cited to appear and answer herein; that upon final trial herein, Plaintiff recovers damages as set forth above from Defendants, including cost of Court, pre-judgment and post-judgment interest at the legal rates, and punitive damages, and that Plaintiff has such other and further relief, both general and special, at law and in equity, to which Plaintiff may be justly entitled under the facts and attending circumstances.

#### DEMAND FOR JURY TRIAL

COME NOW Plaintiff and demands a trial by jury on all issues presented herein.

Signed this 10-th day of Telmany, 2006.

JERE L. BEASLEY (BEA020)

ANDY D. BIRCHFIELD, JR. (BIR006)

NAVAN WARD, JR. (WAR062) PAUL SIZEMORE (SIZ004)

GERALD B. TAYLOR, JR. (TAY026)

# **OF COUNSEL:**

BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C. Post Office Box 4160 Montgomery, Alabama 36103-4160 (334) 269-2343 telephone (334) 954-7555 facsimile

# IN THE CIRCUIT COURT OF COVINGTON COUNTY, ALABAMA

SYLVIA WINGARD as the Administrator	*	
of the Estate of GEORGE WINGARD	*	
Plaintiff,	*	
,	*	
vs.	*	CIVIL NO.
	*	
PFIZER INC., a Delaware Corporation;	*	
PHARMACIA CORPORATION,	*	
a Delaware Corporation; MONSANTO	*	
COMPANY, a Delaware Corporation;	*	
G.D. SEARLE, LLC, a Delaware	*	
Corporation; ALEX DUMOULIN, JR	*	
And fictitious Defendants	*	
A, B, C and D being those persons, firms	*	
or corporations whose actions, inactions,	*	
fraudulent suppression, fraud, scheme to	*	TRIAL BY JURY IS REQUESTED
defraud and/or other wrongful conduct	*	
caused or contributed to the Plaintiff's	*	
injuries and damages, and whose true	*	
names and identities are presently	*	Euro
unknown to the Plaintiff but will be	*	FILED IN OFFICE
substituted by amendment when	*	EFD
ascertained,	*	real a sone
	*	0 0
Defendants.	*	FEB 1 3 2006

# PLAINTIFF'S FIRST SET OF INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS

Pursuant to Rule 33 and 34 of the *Alabama Rules of Civil Procedure*, the Plaintiff propounds the following interrogatories and requests for production of documents to be answered by Defendants G.D. Searle, LLC, Pharmacia Corporation, Monsanto Company and Pfizer, Inc., (hereinafter "Defendants"), in the manner and form prescribed by law:

### **Definitions**

1. "Documents" shall mean writing of every kind, source and authorship, both originals and all non-identical copies thereof, in your possession, custody or control, or known by you to exist,

irrespective of whether the writing is one intended for or transmitted internally by you or intended for or transmitted to any other person or entity, including, without limitation, any government agency, department, administrative entity or personnel. The term shall include handwritten, typewritten, printed, photocopied, photographic or recorded matter. It shall include communications in words, symbols, pictures, sound recordings, films, tapes and information stored in, or accessible through, computer or other information storage or retrieval systems, together with the codes and/or programming instructions and other materials necessary to understand and use such systems.

- For purposes of illustration and not limitation, the term "Documents" shall include: 2. correspondence, transcripts of testimony, letters notes, reports, papers, files, books, records, contracts, agreements, telegrams, teletypes and other communications sent or received, diaries, calendars, logs, notes or memoranda of telephonic or face-to-face conversations, drafts, work papers, agendas, bulletins, notices, circulars, inserts, announcements, instructions, schedules, minutes, summaries, notes and other records and recordings of any conferences, meetings, visits, statements, interviews or telephone conversations, bills, statements and other records of obligations and expenditures, canceled checks, vouchers, receipts and other records of payments, ledgers, journals, balance sheets, profit and loss statements, and other sources of financial data, analyses, statements, interviews, affidavits, printed matter (including published books, articles, speeches and newspaper clippings), press releases, charts, drawings, specifications, manuals, brochures and memoranda of all kinds to and from any persons, agencies or other entities.
- "Identify", when used in reference to a person, means to state that person's full name, 3. name of his or her employer, job title or position, and that person's last known residence and business addresses and telephone numbers.

Any reference to the word medicine, pharmaceutical, drug or product is intended to and 4. shall mean those products known generally as "Bextra (Valedecoxib)" and any and all other trade names or trade marks under which Bextra (Valedecoxib)" have been tested, sold or marketed.

### Interrogatories

- State the legal name of these Defendants, and the names and titles of all persons 1. answering the following discovery on behalf of these Defendants.
- 2. State the relationship between these Defendants and any other Defendants in this lawsuit. Produce any documents that are evidence of such relationship.
- 3. Identify each employee or representative of these Defendants, or independent contractor, who had any responsibility for sales or marketing of Bextra (Valedecoxib) in Jefferson County, Alabama. Intended to be included in the information sought by this interrogatory are the individuals responsible for sales and/or marketing on a statewide, regional and national level. This requests specific areas, with specific boundaries, i.e., counties, cities, south or north of specific highways, etc. which were included in each representative's sales territory.
- State the revenue of these Defendants from the sale of Bextra (Valedecoxib), both 4. cumulatively and for each year since it was first marketed in the United States.
  - a. And, for each person identified in Interrogatory 3 above, please list all revenues directly or indirectly attributable to each person's sales/marketing efforts within their territorial region.
- Identify each person, by name, current business and home address and telephone number. 5. that is most knowledgeable about the following, substantive areas:

- a. The development of Bextra, specifically including, but not limited to its alleged COX-2 selectivity, or COX-2 specific qualities.
- b. Presentation of investigative new drug application to the FDA.
- c. Presentation of new drug application (NDA) to the FDA, including all scientific/pharmacological/toxicological information included therein, as well as all adverse reports.
- d. The selection criteria for all study/investigative study patient participants, including each and every criteria considered for study participation.
- e. Marketing of Bextra internationally, nationally, regionally and within the State of Alabama, including, but not limited to, the frequency and context of all detail calls made within the State of Alabama, and by whom.
- f. Training of inside and outside detail/sales representatives.
- Identify each person whom you anticipate may testify as an expert witness in this action, 6. and for each such person, state:
  - The subject matter on which the expert is expected to testify.
  - b. The substance of the facts and opinions to which the expert is expected to testify.
  - c. A summary of the grounds for each opinion.
  - d. All civil actions or other legal proceedings in which such person has testified, by deposition or at trial, since January 1, 1995, including for each action or proceeding the name of the case, the jurisdiction/court in which such action or proceeding is or was pending, the case number, name and address of opposing counsel, and whether the testimony was by deposition, at trial or other hearing, by affidavit or other sworn declaration, or any combination of the foregoing. In addition, produce a current

resume, curriculum vitae or similar other detailed statement of the person's background and qualifications.

- 7. What instructions were given to your sales representatives for providing information to physicians or responding to physician inquiries about the risks or potential risks associated with Bextra?
- Did these Defendants prepare any information about Bextra for direct dissemination to 8. the patient and/or his/her family, or for other direct advertising or marketing to consumers, including, but not limited to patient hand-out, instructions to doctors for answering patient inquiries, or videos? If so, please produce copies of these materials, and for each set of materials, state the date of initial preparations and the inclusive dates during which such materials were to be used.
- State whether any cost-benefit or similar analyses were performed regarding Bextra. If 9. so, please produce copies of all documents reflecting or relating to any such analysis.
- 10. Identify the names of the agencies, divisions, or committees or other groups within these Defendants' corporation that participated in the developing, manufacturing, distributing, and/or supplying of Bextra, and identify and state the duties of all persons who served on these committees and/or agencies.
- At any time prior to or during the development of Bextra did these Defendants conduct 11. tests or studies of any type, the results of which contain, or possibly contain, or reflect information relative to the possibilities of complications and/or adverse effects which have occurred in patients following the use of Bextra? If so, please state:
  - a. The number of any such tests or studies.
  - b. An accurate description of the tests, prototypes, protocols and/or designs.

- c. The inclusive dates during which any and all such tests or studies were actually conducted.
- d. The test numbers of each and all such tests.
- e. The dates that the report of each such test or study was prepared.
- f. Describe in detail how each such test or study was conducted.
- g. Describe the results of all and each such tests or study with regard to information relative to the possibility of complications.
- h. Identify, for each test or study, all persons who conducted such test or study.
- i. The title or name of the test or study.
- Explain in detail the records, which these Defendants keep of consumer complaints that 12. are made to it. Produce any and all copies of the complaints, regardless of the manner in which originally made, relating to Bextra.
- Give the name, address, and job title of the person employed or retained by these 13. Defendants most familiar with maintaining the records of consumer complaints or adverse event reports that are made regarding Bextra.
- State the full extent of these Defendants' knowledge relating to the hazards, 14. contraindications, side effects and adverse effects, reactions or events relating to the use of Bextra.
- Did these Defendants have specific and/or express knowledge of any adverse events 15. (possibly, probably, or definitely causally related to Bextra in the opinion of, or as concluded, determined, or diagnosed by the reporting source, i.e., the reporting/prescribing/treating physician, any principal or co-investigator, not in the opinion, or as concluded, determined, or diagnosed by Defendants) related to Bextra reported or received from any sources within, or outside the U.S., including but not

limited to, Japan, the Philippines, Great Britain, Australia, Europe, South America, Central America, North America or New Zealand at any time prior to the submission of the NDA for Bextra?

This interrogatory includes, but is not limited to, any adverse event reports or information from foreign human Bextra clinical trials, post-marketing reports or medical journals, seminars, letters, memos, correspondence, personal notes, e-mails or other forms of electronic data transmission. This request includes any information regarding adverse events which were potentially related to Bextra, whether contained or included in the standard U.S. adverse event report form, or a similar form or method of reporting adverse drug events which are used in foreign countries, including but not limited to Japan, Australia, the Philippines, Great Britain, South America, Central America, North America, New Zealand or Europe.

- Please state the date on which Bextra was first marketed in any county, identifying 16. country with date.
- Please identify for these Defendants, for themselves or any of their associated companies, 17. divisions, officers and/or employees, all fines, sanctions, fees or penalty assessments of any type paid to any governmental agency or regulatory authority that in any manner relates to the development and marketing of any drug or pharmaceutical product. Your answer should include information identifying each such payment made by these Defendants, for themselves or any of their associated companies, divisions, officers and/or employees from January 1, 1990 to the present, including the payee, the date of the payment, the amount and how such payment was identified or charged off in the Defendants' accounting records.

- 18. Identify by name, address, telephone number, and employer of each person who, on behalf of these Defendants, had <u>any</u> contact with employees of the FDA regarding Bextra. This interrogatory is intended to encompass and extend beyond a request for the names of employees of Defendants, and is specifically intended to include, but not be limited to, independent contractors and lobbyists that had <u>any</u> contact with the FDA regarding Bextra, whether prior to, during the pendency of, or subsequent to the submission of the NDA relative to Bextra.
- 19. Identify by name, address, telephone number, and employer each person who, on behalf of these Defendants, had <u>any</u> contact with members of Congress or the Senate, or any individual on a Congressperson's or Senator's paid or volunteer staff regarding Bextra. This interrogatory is intended to encompass and extend beyond a request for the names of employees of Defendants, and is specifically intended to include, but not be limited to, independent contractors and lobbyists that had <u>any</u> contact with members of Congress or the Senate, or any individual on a Congressman's or Senator's paid or volunteer staff, regarding Bextra, whether prior to, during the pendency of, or subsequent to the submission of the NDA relative to Bextra.
- 20. Identify by name, address, telephone number, and employer each person who, on behalf of these Defendants, had <u>any</u> contact with members of the Health Care Financing Administration (HCFA) regarding Bextra. This interrogatory is intended to encompass and extend beyond a request for the names of employees of Defendants, and is specifically intended to include, but not be limited to, independent contractors and lobbyists that had <u>any</u> contact with members if the Health Care Financing Administration (HCFA) regarding Bextra, whether prior to, during the pendency of, or subsequent to the submission of the NDA relative to Bextra.

- Give the name, address, and job title of the person employed or retained by these 21. Defendants most familiar with maintaining any and all post-marketing studies, whether initiated, funded or conducted by these Defendants or some other source or entity.
- For each clinical study and/or protocol that was performed in reference to Bextra by or on 22. behalf of any of the Party Defendants or any Party Defendant. related entity, please provide:
  - a. the name, designation or other identifying information about the clinical study/protocol;
  - b. whether the said clinical study/protocol was published;
  - c. if said clinical study/protocol was published, where was it published (what journal) and when was it published?

### **Requests for Production**

Plaintiffs specifically request that these Defendants produce the following:

- The protocol(s) established by Defendants, for the clinical testing of Bextra. 1.
- The written procedures established by Defendants at any time during the development 2. and marketing of Bextra to address reports Defendants or others received from clinical trials or post-marketing experience concerning:
  - Any abnormal kidney function tests. a.
  - Any other indicators concerning kidney toxicity. b.
  - Any reports of renal failure. c.
  - Any reports of congestive heart failure. d.
  - Any reports of gastrointestinal bleeding/hemorrhage. e.
  - Any reports of other bleeding/hemorrhage. f.

- g. Any reports of death.
- h. Any reports of precipitous increases in systemic blood pressure.
- i. Any reports of "myocardial infarctions" (MI).
- j. Any reports of "cerebrovascular accidents" (CVA).
- k. Any reports of allergic and/ or skin reactions.
- 3. The protocols, procedures and guidelines that were employed by Defendants at any time during the clinical trials and post-marketing experience with respect to how the Defendants responded or was to respond to reports received form:
  - a. Consumers.
  - b. Health professionals.
  - c. Others.
- 4. Records sufficient to identify each and every patent holder of the drug marketed as Bextra by name, address, the patent number, the manner in which Bextra is utilized in such patent.
- 5. Each and every contract between these Defendants, other patent holders or others regarding the development, manufacturing and marketing of the drug Bextra.
- 6. Copies of all advertising text whether printed, published on the web, radio, television or otherwise concerning the drug Bextra that was addressed to:
  - a. Physicians.
  - b. Pharmacists.
  - c. Consumers in English text.
  - d. Consumers in Spanish or any other foreign language text.
- 7. The Defendants' records of account that demonstrate the costs incurred or otherwise paid by the Defendants in the development of the drug Bextra. These costs are to be itemized

Defendants' accounting records.

by line item in the manner in which the Defendants accounted internally for its costs and not summarized in any manner beyond those totals or sub-totals created in the

- 8. The Defendants' records of account that demonstrate the costs incurred or otherwise paid by the Defendants in conducting its clinical trials of Bextra.
- 9. The Defendants' records of account that demonstrate the costs incurred or otherwise paid by the Defendants in presenting the drug Bextra to the Federal Drug Administration. This request includes, but is not limited to, all costs incurred or otherwise paid by the Defendants to apply for "fast track" status, to present information to the advisory panel(s), to hire consultants (including counsel) or representatives and other incidental costs.
- 10. All adverse reports maintained by the Defendants regarding Bextra.
- The complete records of each investigation conducted by the Defendants, or on behalf of 11. the Defendants, in response to the reports responsive to Request for Production 10 above.
- True and complete copies of all press releases and public statements made by the 12. Defendants or on its behalf with regard to Bextra from its inception to the present.
- 13. True and complete copies of the transcripts of any/all statements and appearances made by or on behalf of these Defendants before the Federal Drug Administration concerning Bextra.
- True and complete copies of the records of all proceedings of the FDA whether 14. advisory panel or otherwise - concerning Bextra that are in the possession of Defendants or its agents.

- The complete text of all drafts and final versions of the product information leaflets or 15. brochures that were intended for publication or other distribution to doctors, pharmacists and/or consumers concerning Bextra.
- 16. The complete text of all drafts and final versions of correspondence that Defendants directed to physicians concerning Bextra from its inception to the present.
- The complete text of all drafts and final versions of statements that Defendants have 17. made to its stockholders concerning the development and marketing of Bextra, any adverse effect reports and/or any FDA mandated warnings that were to accompany Bextra.
- The Defendants' records showing its projection of sales of the drug Bextra in any and all 18. markets. These records are to be produced in the most detail accumulated by Defendants in the ordinary course of business
- The Defendants' records showing the actual sales of the drug Bextra in any and all 19. markets. These records are to be produced in the most detail accumulated by Defendants as well as any summaries of that data, kept in the ordinary course of business.
- All insurance agreements or policies under which a person transacting insurance may be 20. liable to satisfy part or all of a judgment which may be entered in this civil action or to indemnify or reimburse for payments made to satisfy the judgment. It is further requested that a verified or attested copy of the declaration sheet relating to any of the aforementioned insurance policies also be produced.
- All documents or records of the Defendants relating to any advertisements for Bextra, 21. whether in professional journals or not.
- All documents concerning any warnings, instructions for use, or other matters concerning 22. the use and/or consumption and possible health risks regarding Bextra.

- 23. All correspondence and documents evidencing any communication, in any form between or among any and all of the Defendants concerning Bextra.
- 24. All drafts of documents containing instructions or warnings for the ultimate consumers of Bextra. (For each such document, state the effective date or inclusive dates for distribution of use of such instructions or warnings.)
- 25. All documents concerning any changes, modification, alteration, and/or reformation of Bextra, including changes to product packaging and product inserts.
- 26. All documents of the Defendants showing quality control, testing, analysis and health studies such as indications, contradictions, side effects, interactions, and adverse experiences, effects, or events concerning Bextra.
- 27. All agreements entered into between or among any of the Defendants.
- 28. All published literature in the possession of the Defendants concerning Bextra.
- 29. Any documents of which Defendants has knowledge of concerning or relating to the adverse reactions, experiences, effects or events regarding Bextra.
- 30. All documents relating to adverse reaction, experiences, effect or event reports as well as investigations of the same, including all notes, memos, letters, reports, files, articles, or any written or computer generated or stored information from any person or source whatsoever, authored as a consequence of the result of any such investigation which discusses, relates or concerns the adverse reaction of Bextra.
- 31. All documents sent to the FDA regarding Bextra.
- 32. All documents received from the FDA concerning Bextra.
- 33. Copies of any warnings, precaution, informational letters, promotions, detail ads, which discuss Bextra. (For each such document, state the effective date or inclusive dates for distribution or use of such document.)

- 34. Copies of all 10K's filed by or concerning these Defendants from 1990 through the present.
- 35. Copies of all annual reports to shareholders of these Defendants from 1990 through the present.
- 36. Copies of all package inserts for Bextra. (For each such document, state the effective date or inclusive dates for distribution or use of such document.)
- 37. Copies of all documents which indicate, discuss or show the following:
  - Gross sales of these Defendants, cumulatively and/or for each year since Bextra was first marketed in the United States.
  - Gross sales for Bextra, cumulatively and/or for each year since Bextra was first marketed in the United States.
- 38. Please identify the full names and corporate titles and addresses of the employees of these Defendants having the most significant responsibilities for the development, licensing and marketing of Bextra, and as to each such person, state the job titles, the inclusive dates during which such person held that job title, and describe briefly the area of responsibility with respect to Bextra.
- 39. Please provide the text of any and all warnings or instructions to physicians and/or patients and consumers about the adverse effects in connection with Bextra, and explain in detail any variation in terminology regarding side effects, contraindications, precautions and warnings. (For each such document, state the effective date or inclusive dates for distribution or use of such document.)
- 40. Any and all studies regarding the safety and effectiveness of Bextra.
- 41. All reports and other documents provided to the FDA or other governmental organization regarding complications, contraindications, hazards, side effects, or adverse experiences,

- effects or events from the use of Bextra, whether used as monotherapy or in conjunction with any other therapy.
- Provide a detailed privilege log of all documents that have been removed from any file or 42. not produced because of a claimed privilege, work product doctrine, trade secret or confidential business information, or other privilege or basis for nondisclosure. Identify each document with such specificity that Plaintiff may fashion a particularized motion to compel as to each non-disclosed document.
- 43. If these Defendants have relied upon or referred to any document in answering any interrogatory, please attach copies of each such document to your answers.
- Documents reflecting the exact total number of patients worldwide, including but not 44. limited to those in Japan, the U.S., the Philippines, Australia, Great Britain, Europe, South America, Central America, North America and New Zealand, which Defendants determined, concluded, acknowledges, admits, concedes, or in its own opinion, believes or suspects, died from or suffered myocardial infarction, cerebrovascular accidents, allergic and or skin reactions, or internal bleeding, caused by Bextra from the date the NDA for Bextra was submitted to the FDA on, through and including the date of these Defendants' response to this discovery.

This includes deaths which occurred during human clinical trials or during the postmarketing period in any foreign country including, but not limited to, the Philippines, Australia, Great Britain, Europe, South America, Central America, North America and New Zealand. This includes any patients who were withdrawn from any clinical trial for any reason, medical or otherwise, whether or not the Defendants believe the injury or deaths as causally related to Bextra.

- 45. A copy of the entire patient case study file and medical records, including autopsy reports, for each death case included in the response to the preceding request (#44), including the patient study number.
  - This request does not include any personal identification information about each patient. Please redact names, addresses, dates of birth, social security numbers, etc., so as to not violate the patient privacy or physician-patient privilege.
- Documents reflecting the exact total number of worldwide patients which Defendants 46. determined, concluded, acknowledges, admits, concedes, or in its own opinion, believes or suspects experienced any adverse events, including, but not limited to, death, myocardial infarction, cerebrovascular accidents, allergic and/ or skin reactions, hypertension or increased hypertension, or gastro intestinal or esophageal bleeding, as a result of Bextra at any time from the date of the first human Bextra clinical trials and post-marketing experience, whether conducted in the U.S. or abroad, including but not limited to Japan, Great Britain, the Philippines, Australia, Europe, South America, Central America, North America and New Zealand to the date of this request which were reported to the FDA in the IND/NDA for Bextra.

This includes any patients who were withdrawn from any clinical trial for any reasonmedical or otherwise, whether or not Defendants believe the abnormalities were causally related to Bextra.

A copy of the entire patient study file and medical records for each patient identified in 47. the preceding request (#46) who were reported to the FDA in the IND/NDA to Bextra. This request does not include any personal identification information about the patients. Please redact names, addresses, dates of birth, social security numbers, etc., so as to not violate the patient privacy or physician-patient privilege.

- 48. Documents reflecting the total number of clinical trial patients who began each separate human Bextra clinical study, including, but not limited to those within the U.S., Japan, Great Britain, the Philippines, Australia, Europe, South America, Central American, North America and New Zealand who were withdrawn from the study or did or did not complete it for any reason, regardless whether or not Defendants believe the reason for the withdrawal was not causally related to Bextra. Please identify the patient study number of each patient who was withdrawn.
- 49. A copy of the entire patient case study file and medical records for each patient who was withdrawn or otherwise did not complete the clinical trial who is included in the preceding request (#47). This request does not include any personal identification information about the patients. Please redact names, addresses, dates of birth, social security numbers, etc., so as to not violate the patient privacy or physician-patient privilege.
- 50. All tangible and electronic correspondence sent to and received from any person involved in each separate clinical trial study for Bextra worldwide, including, but not limited to, the U.S., Japan, the Philippines, Australia, South America, Central America, North America and New Zealand, including, but not limited to, principal investigators, co-investigators, co-investigators, sub-investigators, technicians, their staff or any other person who in any way participated in the clinical trials. This includes, but is not limited to, any and all letters, reports, e-mails or any other source tangible data transmission, whether electronic or otherwise.

This includes, but is not limited to, adverse events, general observations of results during trials, preliminary study reports, or any other reference to results, problems, successes, general correspondence about Bextra, observed during clinical trials.

- All tangible and electronic internal correspondence, person specific and/or general, including but not limited to, memos, e-mails, or other electronic data transmissions, to and from all sales and marketing personnel employed by, retained by, associated with or in any way affiliated with Defendants, which in any way discusses, relates to, or involves potential safety concerns with prescribing physicians and pharmacists, sales strategies, marketing and advertising regarding Bextra.
- 52. An entire copy of each and every Bextra patient case study file, including, but not limited to, the patient's medical records and the adverse event report, for each and every adverse event report ever received by or reported to Defendants prior to February 28, 2001, from any source, including, but not limited to, human Bextra clinical trial studies, both within the United States and abroad, including, but not limited to, Japan, the Philippines, Australia, South America, Great Britain, Europe, Central America, North America and New Zealand which Defendants determined or concluded was definitely, probably, or possibly, not causally related to Bextra and which was not included in the IND/NDA for Bextra or reported or provided to the FDA thereafter through the date of this request.
- An entire copy of each and every Bextra patient case study file, including, but not limited to, the patient's medical records and the adverse event report, for each and every adverse event report ever received by, or reported to Defendants, from any source, including, but not limited to, human Bextra clinical trial studies, both within the United States and abroad, including, but not limited to, Japan, the Philippines, Australia, South America, Great Britain, Europe, Central America, North America and New Zealand, which Defendants determined was definitely, probably, or possibly, not causally related to Bextra and which was not reported or provided to the FDA thereafter through the date of this request.

- An entire copy of each and every Bextra patient case study file, including, but not limited to, the patient's medical records and the adverse event report, for each and every adverse event report ever received by, or reported to Defendants, from any source, including, but not limited to, human clinical trial studies, both within the United States and abroad, including, but not limited to, Japan, the Philippines, Australia, South America, Great Britain, Europe, Central America, North America and New Zealand, which Defendants determined was definitely, probably, or possibly causally related to Bextra and which was not included in the IND/NDA for Bextra, or reported to the FDA thereafter through the date of this request.
- An entire copy of each and every Bextra patient case study file, including, but not limited to, the patient's medical records and the adverse event report, for each and every adverse event report ever received by, or reported to Defendants from any source, including, but not limited to, human Bextra clinical trial studies, both within the United States and abroad, including, but not limited to, Japan, the Philippines, Australia, South America, Great Britain, Europe, Central America, North America and New Zealand, which Defendants determined was definitely, probably, or possibly causally related to Bextra and which was reported to the FDA thereafter through the date of this request.
- Any and all internal memos, internal or external correspondence and e-mails, including, but not limited to, any form of electronic data transmission to, or from Defendants, including, but not limited to, any employee, agent, director, officer or other personnel under the direct control of Defendants, to, or from, any other personnel, including, but not limited to, any persons involved in the clinical trials for Bextra, other clinical researchers, physicians, patients, the FDA or any other regulatory agency, or any other Defendants herein, which in any way discuss, involve, or relate to the decision to market

- Bextra, and specifically as a COX-2 selective NSAID medication. This includes all information generated from the date of the first report of adverse events in the U.S. or abroad, through the date of this request.
- 57. Any and all internal correspondence, memos and e-mail or other electronic data transmission, to the date of this request, to or from Defendants' sales and marketing staff and personnel, including, but not limited to, Bextra drug sales representatives, detail personnel and their managers, which in any way relates to, involves, or discusses what information regarding adverse events, should or should not be provided to, or discussed with, prescribing physicians, pharmacists or clinical investigators or their staff.
- Any and all correspondence, memos, e-mails or other forms of electronic data transmissions, to or from any external source (i.e., generated by someone who is not an agent, servant, employee, director, officer or other personnel under the direct control of Defendants), including, but not limited to, principal investigators and their staff, prescribing physicians or pharmacies, which in any way discusses, involves or relates to specific adverse events or general patient health concerns related to Bextra.
- 59. Any and all internal memos, correspondence, e-mails or other electronic data transmissions to or from any agent, employee, officer, director or other person under the direct control of Defendants, or acting for or on Defendants' behalf, which in any way discusses, involves, or relates to the Defendants' denial of, conscious refusal to concede, admit, conclude, acknowledge, or express any opinion, publicly or privately, that Bextra caused any health problems or injuries.
- 60. Documentation of any and all direct, or indirect, compensation paid to any principal or co-investigators, their staffs, families, or any other persons associated with the clinical trial studies of Bextra for any reason. This includes, but is not limited to, copies of direct

Case 2:06-cv-00254-ID-SRW

cash payment youchers, canceled checks, money orders, wire transfers, indirect compensation such as travel expenses, meals, entertainment, gifts or honorariums, and also including, but not limited to, any and all forms of valuable consideration including securities and equities in Defendants' company or any company legally associated or affiliated with Defendants' company, including, but not limited to, stock ownership, options, warrants, bonds or other securities, which the recipient realized a tangible economic value at the time of the receipt or thereafter.

- Documentation of any and all direct, or indirect, compensation paid to any physicians, 61. their staffs, families, or any other persons associated with the clinical trial studies of Bextra for any reason. This includes, but is not limited to, copies of direct cash payment vouchers, canceled checks, money orders, wire transfers, indirect compensation such as travel expenses, meals, entertainment, gifts or honorariums, and also including, but not limited to, any and all forms of valuable consideration including securities and equities in Defendants' company or any company legally associated or affiliated with Defendants' company, including, but not limited to, stock ownership, options, warrants, bonds or other securities, which the recipient realized a tangible economic value at the time of the receipt or thereafter.
- A copy of all expenses related to travel and entertainment (as defined by the applicable 62. Internal Revenue Code Section) paid by Defendants directly, or indirectly, to, or on behalf of any clinical investigation personnel, their staff or families, associated with the clinical trial studies of Bextra. This includes, but is not limited to, payment for any and all expenses related to seminars conducted or sponsored, in whole or in part, by these Defendants, their wholly owned subsidiaries, products, drugs or services; gratuitous tickets to entertainment events such as sporting events, arts, general entertainment

- (operas, plays, etc.), payment for meals, personal gifts or any other goods or services in which the recipient received an indirect economic benefit.
- A copy of the minutes of each and every committee meeting held by Defendants that in 63. any way related to Bextra, including, but not limited to, pre-marketing safety concerns, adverse events, marketing strategies, potential market penetration, potential profits, potential sales, strategies regarding how to respond to and deal with FDA concerns, strategies to persuade any person that adverse events related to Bextra were not serious and should be dismissed, ignored or downplayed; package insert revision discussions, or any other subject matter related to the research, development, marketing, sales and safety concerns relating to Bextra.
- Any and all documentation of the account of the gross and net profits, including all 64. incurred expenses, received by, and incurred by Defendants, relating to the sale and marketing of Bextra worldwide. This specifically requests the Defendants' own accounting calculations of gross sales, expenses, net profits and other financial effects or impacts of Bextra on Defendants' ongoing profits and operation, on an annual basis from 1999 to the date of this request.
- All information sent by Defendants to pharmacies or drug distribution centers within the 65. U.S. which in any way relate to, involve, or discuss Bextra from January 1, 1998, through the date of this request. This includes, but is not limited to, letters, announcements, reports, original package inserts and all revisions, and adverse event reports. (For each such document, state the effective date or inclusive dates for distribution or use of such document.)

66. A copy of all licensing agreements between these Defendants and any other entity relating to the research and development, production, distribution, sales and marketing, or other mutual involvement relating to Bextra.

Case 2:06-cv-00254-ID-SRW

- 67. A copy of all marketing agreements between these Defendants and any other entity relating to the research and development, production, distribution, sales and marketing, or other mutual involvement relating to Bextra.
- 68. A copy of all profit sharing, expense sharing or other financial agreements between these Defendants and any other entity, relating to the research and development, production, distribution, sales and marketing, or other mutual involvement relating to Bextra.
- 69. Any and all partnership agreements, joint venture agreements, co-development agreements, or other documented legal agreements between Defendants and any other entity regarding the research and development, distribution, sales and marketing or other involvement of Bextra.
- 70. Any and all written settlement agreements with any plaintiff or claimants, whether based on pre-litigation claims or filed lawsuits relating to, or involving allegations that health related injuries were caused by Bextra, whether within the U.S. or other foreign country.
- 71. The original petition(s) or complaint(s), including style, cause number and all plaintiffs or claimants of all lawsuits ever filed against Defendants relating to allegations that Bextra caused injury or adverse events, whether in the U.S., or abroad.
- Produce all memos, documents, tables, graphs, tests, test results or other illustrative or explanatory material by whatever name known or characterized by these Defendants in their normal course of business, which discusses or illustrates the relationship between COX-2 selectivity and therapeutic dosing.

- 73. Documents reflecting all epidemiological, clinical or double-blind placebo trial, test or study results that document or illustrate the relationship between COX-2 selectivity of Bextra and therapeutic dosing levels.
- 74. Documents reflecting any and all post marketing surveys or studies completed by these Defendants regarding Bextra whether or not the post marketing study or survey was undertaken, performed or funded by these Defendants.
- 75. Any and all documents, letters correspondence, e-mail, facsimile, press release or other written, verbal, electronic or other communication made by Defendants, or any employee, agent, representative, independent contractor or otherwise, acting on their behalf, that was transmitted or communicated from Defendants to any news industry or financial industry representative, or with the knowledge that the ultimate recipient would be a person acting for or on behalf of any person, firm or corporation within the news or financial industry. This request is intended to included, but not be limited to, all communications by or on behalf of Defendants and members of the print and broadcast news industry and the members of the financial industry; including, but not limited to, news, press or financial information; product launch information; or INDA/NDA information disseminated to ABC, NBC, CBS, CNBC, FOX, Fox News, The Wall Street Journal, Fortune Magazine, Money Magazine, any other financial or non-financial newspaper, periodical or publication, any bank, brokerage house/firm, or other financial institution or institutional investment corporation, whether for purposes of stock/bond underwriting, pursuant to financing conditions of underwriting or not, or for general dissemination of product news.

- Please produce the drug safety/adverse event database for Bextra. The drug safety/adverse 76. event database for Bextra should include, but not limited to, reports of all worldwide drug safety/adverse events reported concerning the safety of Bextra to the Defendants since Bextra was approved in November 2001.
- Please produce the clinical trials database for Bextra. The clinical trials database for 77. Bextra should include, but not limited to, records of all the clinical trials concerning the safety of Bextra.
- Please produce the marketing/sales representative database for Bextra. The 78. marketing/sales representative database for Bextra should include, but not limited to, information concerning the Defendants' marketing strategy for Bextra, information Defendants' sales force was instructed to distribute to physicians concerning the safety of Bextra and call notes and/or questions from physicians to the Defendants' sales force concerning the safety of Bextra.
- Please produce the medical database for Bextra. The medical database for Bextra should 79. include, but not limited to, reports of all questions/inquires made by physicians about the safety of Bextra to defendants.

JERE L. BEASLEY (BEA020)

ANDY D. BIRCHFIELD, JR. (BIR006) NAVAN WARD, JR. (WAR062)

PAUL SIZEMORE (SIZ004)

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## SERVED UPON DEFENDANTS WITH SUMMONS & COMPLAINT